

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE PROCTER & GAMBLE COMPANY,)	
)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 04-940-JJF
)	
TEVA PHARMACEUTICALS USA, INC.,)	
)	
Defendant.)	

[PROPOSED] PRETRIAL ORDER

This matter having come before the Court for a pretrial conference pursuant to Fed. R. Civ. P. 16 and Local Rule 16.4; Frederick L. Cottrell III, Esq., Steven J. Fineman, Esq., William F. Lee, Esq., David B. Bassett, Esq., and Vinita Ferrera, Esq. having appeared for plaintiff, The Procter & Gamble Company ("P&G"); and James Galbraith, Esq., Maria Luisa Palmese, Esq., A. Antony Pfeffer, Esq., Josy W. Ingersoll, Esq. and Karen L. Pascale, Esq. having appeared for defendant Teva Pharmaceuticals USA, Inc. ("Teva USA"), the following Final Pretrial Order is hereby entered:

1. STATEMENT OF THE NATURE OF THE ACTION

P&G is the owner by assignment of U.S. Patent No. 5,583,122, entitled "Pharmaceutical Compositions Containing Geminal Diphosphonates" (the "122 patent"), which issued on December 10, 1996. This action relates to an Abbreviated New Drug Application ("ANDA") filed by Teva USA (ANDA No. 77-132) with the U.S. Food and Drug Administration ("FDA") for approval to market drug products containing as their active ingredient risedronate sodium monohydrate. These products are a generic version of P&G's ACTONEL® drug products, which contain as their active ingredient risedronate sodium hemipentahydrate. On August 13,

2004, P&G brought a patent infringement suit against Teva USA under the U.S. Patent Laws seeking to enjoin the approval of Teva USA's ANDA and the manufacture, use, sale, offering for sale, or importation of its proposed risedronate sodium monohydrate drug products until the expiration of the '122 patent.

P&G's infringement claims are set forth in its First Amended Complaint. In response to the First Amended Complaint, Teva USA asserted various defenses, including non-infringement and invalidity of the '122 patent under 35 U.S.C. §§ 102, 103, and 112. P&G is asserting claims 4, 12, 14, 16, and 23 of the '122 patent in this action. To streamline discovery and reduce the issues for trial, Teva USA has agreed to stipulate to infringement of the asserted claims for purposes of this litigation only.

2. **JURISDICTION**

This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a).

3. **STATEMENT OF FACTS WHICH ARE ADMITTED AND REQUIRE NO PROOF**

The Parties' Joint Statement of Admitted Facts Requiring No Proof is attached as **Tab 1**.

4. **ISSUES OF FACT THAT REMAIN TO BE LITIGATED**

P&G's Statement of Issues of Fact that Remain to be Litigated is attached as **Tab 2**.

Teva USA's Statement of Issues of Fact that Remain to be Litigated is attached as **Tab 3**.

5. **ISSUES OF LAW THAT REMAIN TO BE LITIGATED**

P&G's Statement of Issues of Law that Remain to be Litigated is attached as **Tab 4**.

Teva USA's Statement of Issues of Law that Remain to be Litigated is attached as **Tab 5**.

6. **LIST OF PRE-MARKED EXHIBITS**

P&G's list of pre-marked exhibits, along with Teva USA's objections is attached as **Tab 6**.

Teva USA's list of pre-marked exhibits, along with P&G's objections is attached as **Tab 7**.

The parties have agreed that the demonstrative exhibits the parties intend to use at trial do not need to be included on their respective lists of trial exhibits. The parties shall exchange copies (using best efforts to exchange color copies) of demonstrative exhibits and shall make available for inspection physical exhibits to be used at trial, labeled with the exhibit number, as set forth below. Exchange of large boards or transparencies is not required, and these exhibits may be exchanged on 8 ½ by 11-inch white paper. Any demonstrative exhibit, except for demonstrative exhibits used for impeachment, or created during testimony of a witness or during opening and closing statements, shall be exchanged by 6:00 PM the evening prior to its anticipated use, unless the parties agree to alternate arrangements.

The parties will offer as exhibits at trial one or more of the exhibits set forth in their respective exhibit lists. These lists include the exhibit numbers to be used at trial and a description sufficient to identify the exhibits. The parties will exchange premarked exhibits through local counsel two weeks prior to trial, unless otherwise agreed to by the parties. These exhibit lists may include exhibits that may not be introduced into evidence. A party's failure to introduce an exhibit appearing on its list shall not be commented on during trial.

Any document, deposition, or portion thereof not specifically identified on an exhibit list or not offered into evidence still may be used at trial for the purposes of cross-examination, impeachment, or rehabilitation, if otherwise competent for such purposes.

Legible photocopies of United States Patents may be offered and received into evidence

in lieu of certified copies thereof, subject to all other objections which might be made to the admissibility of certified copies. Legible photocopies of United States Patent Applications, and the contents of associated Patent and Trademark Office File Histories, to which issued United States Patents claim priority, may be offered and received into evidence in lieu of certified copies thereof, subject to all other objections which might be made to the admissibility of certified copies. The dates of filing and issuance, the identity of the inventors of record and the ownership of such patents (or applications) shall be deemed to be as shown on the face of the patent (or application), subject to the right of the party against whom it is offered to adduce evidence to the contrary.

7. **WITNESSES**

The witnesses that P&G intends to call at trial are listed at **Tab 8**.

The witnesses Teva USA intends to call at trial are listed at **Tab 9**.

The listing of a witness on a party's witness list does not require that party to call that witness to testify, either live or by deposition.

8. **DEPOSITION DESIGNATIONS**

P&G's designations and counterdesignations of deposition testimony to be presented at trial are attached as **Tab 10**.

Teva USA's designations and counterdesignations of deposition testimony to be presented at trial are attached as **Tab 11**.

9. **BRIEF STATEMENT OF INTENDED PROOFS**

P&G's Statement of Intended Proofs is attached as **Tab 12**.

Teva USA's Statement of Intended Proofs is attached as **Tab 13**.

10. **ANY AMENDMENTS OF THE PLEADINGS DESIRED BY ANY PARTY**

At this time neither party is seeking any amendment of the pleadings.

11. **OTHER MATTERS**

Procter & Gamble would like to discuss the admissibility of Teva USA's expert on the issue of commercial success, Jesse David, which is the subject of P&G's Motion in Limine to Strike the "Expert Report of Jesse David, Ph.D." (Docket No. 66). Although P&G disagrees with the characterization of the issues set forth by Teva USA below, P&G will be prepared to address and respond to each of these issues at the Pretrial Hearing.

Teva USA would like to discuss the following issues at the Pretrial Conference:

- 1) Order of proof at trial.
- 2) Whether P&G may call a "patent law expert" at trial, which is the subject of Teva USA's Motion to Preclude the Testimony of Plaintiff's Patent Law Expert. (Docket Entry 69).
- 3) The inadmissibility of documents produced by P&G months after close of discovery and practically on the eve of the due date for this Pretrial Order, and any testimony relating to the subject matter of those documents. Teva USA reserves to the right to ask for further relief regarding P&G's belated document production once it has had a chance to more carefully review the documents.

In addition Teva USA opposes P&G's motion regarding the Expert Report of Dr. Jesse David, and will be prepared to address it at the Pretrial Hearing.

THIS ORDER SHALL CONTROL THE SUBSEQUENT COURSE OF THE ACTION
UNLESS MODIFIED BY THE COURT TO PREVENT MANIFEST INJUSTICE.

/s/ Karen L. Pascale

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Dated: July 10, 2006

/s/ Steven J. Fineman

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DATE

UNITED STATES DISTRICT JUDGE